REMARKS

It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims remaining in this application be allowed.

Claim Amendments

No claims are being amended at this time. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Rejection Under 35 U.S.C. §103(a)

Claims 25 and 27-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al. (US 2002/0090339) in view of Paterson et al. (US 2004/0224864) or Porter et al. (US 2004/0197302). The rejections are maintained for reasons of record in the previous office action filed on July 20, 2009 and December 24, 2009, and April 9, 2010.

Before presenting arguments, applicants would like to summarize important background of the current invention.

Problem solved by current invention.

When using embolizing compositions to occlude vascular lesions or structures from systemic blood flow, the volume of the composition delivered is critical. In the example of an aneurysm, the amount of embolic composition delivered is selected to substantially fill but not overflow the aneurysmal sac. If less than this amount of embolic composition is delivered to the aneurysmal sac, the patient will be left with an active aneurysm. In some cases, this can be more dangerous than the untreated aneurysm. If the amount of embolic composition delivered is greater than what is required to fill the aneurysm, the composition will overflow into the adjoining blood vessel. In the case where the affected blood vessel is in or leads to a critical body organ, such as the brain, permanent damage due to the resulting ischemia can result.

The addition of a water-insoluble contrast agent allows for visualization of the amount of embolic composition being delivered to the aneurysm. Typical embolic compositions employ a less than 40 weight percent of contrast agent. While these compositions are useful in most cases, there are occasions where greater visibility of the *in vivo* formed precipitate is desired.

One method of improving the visibility of the composition is to add a higher weight percentage of water-insoluble contrast agent. However, there are obstacles preventing the use of an increased amount of contrast agent. These include:

1. A reduction in the flowability of the composition. Embolic compositions are typically delivered through microcatheters. Accordingly, the increased amount of water-insoluble contrast agent may result in a composition with inadequate flowability (e.g. due to enhanced likelihood of catheter plugging arising from the use of more insoluble contrast agent). Such clogging would result in failure of the embolization procedure.

2. Lack of cohesiveness in the precipitate formed *in vivo*. It is believed that the precipitate formed *in vivo* is a matrix of water-insoluble contrast agent encapsulated within the water-insoluble biocompatible polymer. Increasing the amount of water-insoluble contrast agent may result in a precipitate that fragments *in vivo*. In this situation, the fragmented precipitate may travel to other organs and cause ischemic events due to an occlusion in the blood flow to the organ. Therefore, an embolic composition must form a cohesive precipitate *in vivo*.

For these reasons, an embolic composition with an increased weight percentage of contrast agent must somehow overcome these obstacles. The present invention provides improvement over the prior art because it allows for improved visibility while maintaining flowability of the composition and the cohesiveness of the precipitate formed *in vivo* without the addition of other elements in the composition.

As noted in the claims, the embolic compositions of this invention have a high viscosity, and flowability of such high viscosity compositions is important. Central features of this invention as they relate to high viscosity compositions include a) that flowability is permitted

when using no more than 60 weight percent of the tantalum contrast agent having an average particle size of about 5 microns or less and b) the *in vivo* formed precipitate maintains cohesiveness provided that there is a defined amount of polymer relative to the contrast agent. This latter requirement is defined in the claims as a ratio of ethylene vinyl alcohol copolymer to the tantalum contrast agent being from 0.077 to 0.90.

Prior Art

Whalen et al. (US 2002/0090339) teaches embolic compositions comprising: a biocompatible polymer at a concentration of from about 2 to about 50 weight percent; and a biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent; and a biocompatible solvent from about 10 to about 88 weight percent (abstract and paragraphs [0032]-[0035]).

Porter et al. (US 2004/0197302) teaches a rheologically-modified composition comprising a solution of about 3 to about 12 weight percent of biocompatible prepolymer, about 20 to about 55 weight percent of a contrast agent, more preferably about 37 to about 40 percent contrast agent and about 3 to about 12 percent rheological modifier (paragraphs [0053] and [0069]).

Patterson et al. (US 2004/0224864) teaches a composition of a biocompatible polymer 1 to 12%, a contrast agent 20 to 55%, and fumed silica (a rheological modifier) 1 to 12% (paragraph [0193]).

As to the above, the only references that teach greater than 40 weight percent of water-insoluble contrast agent further employ a rheological modifier. See for example both Porter and Patterson. Applicant notes that the use of a rheological modifier alters the viscosity of the composition in a manner that the viscosity is significantly reduced during stress. Porter and Patterson both use rheological modifiers so that an otherwise non-flowable compositions becomes flowable under stress. Stress occurs when the composition is pushed through the catheter.

As is well known, the term "consisting essentially of" eliminates materials that significantly alter the composition.

As to Porter and Patterson, the addition of a rheological modifier alters the composition to allow it to be more flowable. In the absence of the rheological modifier, the flowability concerns arising from a higher weight percent of contrast agent have yet to be met but for this invention.

Claims 25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al. (US 2002/0090339) in view of Dure-Smith et al. (US 3,937,800).

This rejection is in error for similar reasons as those discussed above. As described previously, the present invention is an improvement over the prior art because it allows for improved visibility ***and*** maintained flowability of the composition and maintained cohesiveness of the precipitate without the addition of other elements in the composition.

The Whalen application, as previously discussed, fails to teach a specific concentration of tantalum contrast agent from about 45 to no more than 60 weight percent in the composition.

The Dure-Smith patent teaches an X-ray contrast media composition containing tantalum metal ranges from about 20% to about 70% by weight (col. 3 lines 3-6 and col. 6 lines 10-15). The Dure-Smith patent also discloses that "physiologically and pharmaceutically acceptable amount of X-ray opaque ingredient which when combined with common contrast media ingredients of a non-opaque nature (suspending agent, viscosity builder, surfactant, etc.) will give a smooth, flowable, evenly dispersed contrast media" at column 2, lines 63-65.

The oily compositions and aqueous suspension disclosed in Dure-Smith are formulated to be administered by insufflation of 10-20 ml of composition by aerosol into the lung to coat the mucosal ling of the bronchial tree. See for example, Column 1, lines 5-6 and column 1 lines 46-49. These compositions of Dure-Smith are not for direct intravascular microcatheter injection, as they would not be compatible with blood and could form insoluble droplets. Thus, the

compositions of the Dure-Smith application are not relevant to the invention as claimed in this patent application.

Furthermore, neither the Whalen nor the Dure-Smith publications suggest a ratio of elements in the composition that would arrive at the achieved result in the instant invention.

This invention achieves flowability by using a water-insoluble contrast agent of a specific size at a maximum amount. Such is not taught by any of the references described above. Moreover, the cohesiveness properties of the compositions of this invention require the ratio of ethylene vinyl alcohol copolymer to the tantalum contrast agent being from 0.077 to 0.90. Absent a teaching or suggestion of such a ratio, the rejection is in error, and it is respectfully requested that this rejection be withdrawn.

Obviousness-Type Double Patenting Rejection

Claims 25-29 are rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,667,767 and claims 1-8 and 16-23 of U.S. Patent No. 5,695,480 are maintained for reasons of record in the previous office action filed July 20, 2009 and December 24, 2009.

Applicants again maintain that none of the cited references teach or suggest a contrast agent concentration of from about 45 to no more than 60 weight percent. At best, the prior art teaches a maximum of about 40 weight percent tantalum. Furthermore, the art teaches that preferred embodiments use less than 40 weight percent tantalum. Such would teach away from the currently claimed range found in now presented Claim 25.

Finally, in making this rejection, the Office has twice failed to specifically provide any rationale as to why the skilled artisan would construe the term "about 40%" to read on about 45 to no more than 60 weight percent.

In view of the above, withdrawal of this rejection is requested.

Conclusion

Allowance of claims 25 and 27-29 is requested. Not withstanding the above and in order to avoid abandonment, a notice of appeal is incurred herewith.

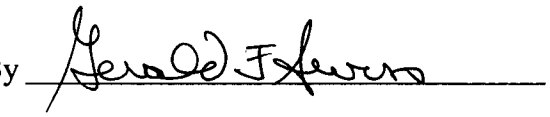
Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date February 22, 2011

By 

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